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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,204	08/20/1999	ROBERT TAM	216/013-US1	1379

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ROBERT D. FISH; RUTAN & TUCKER, LLP
P.O. BOX 1950
611 ANTON BLVD., 14TH FLOOR
COSTA MESA, CA 92628-1950

[REDACTED] EXAMINER

SCHULTZ, JAMES

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1635

DATE MAILED: 05/07/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/331,204	TAM, ROBERT	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 March 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4, 6-17 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6-10, 17 and 19-25 is/are rejected.
- 7) Claim(s) 11-16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 July 1999 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

The terminal disclaimer filed on March 18, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Number 5,932,556 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicant's response filed March 18, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed December 18, 2002 are hereby withdrawn. Applicants' amendment of claims 1 and 17 has been noted and fully entered. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Response to Arguments

Claims 17, and 19-25 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for aptamer-mediated inhibition of SP1 *in vitro*, does not reasonably provide enablement for said inhibition *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the same reasons as set forth in the Office action dated June 18, 2002.

Applicants argue that the amendment submitted March 18, 2003 obviates the instant enablement rejection, because Applicant's amendment now reads on medicating an

immunocompetent cell as opposed to claiming methods of treating disease. Applicants claim the language of medicating an immunocompetent cell is clearly enabled by the specification, both for *in vivo* and *in vitro*.

This argument is not considered convincing. Applicants' claimed methods still encompass *in vivo* applications. Contrary to applicants' arguments, and as set forth in the Office action dated June 18, 2002, applicants' claimed methods that encompass *in vivo* applications are not enabled by the instant specification. The guidance given in the specification regarding *in vivo* use is solely prophetic in nature, with no exemplification provided in any *in vivo*-analogous model system. When such prophetic guidance is taken in view of the prior cited references of the pending enablement rejection, which indicate that one of skill cannot reliably extrapolate from results obtained *in vitro* cell culture systems to predict what will happen *in vivo*, it is apparent that one of skill would have to resort to trial and error experimentation to practice applicants invention *in vivo* with no reasonable assurance of any success. Applicant has provided no arguments or evidence to rebut the *prima facie* case of lack of enablement other than the assertion that the instant claims are enabled *in vitro* and *in vivo*; accordingly and in view of the evidence set forth previously, the rejection of the prior Office action is maintained.

Claim Rejections - 35 USC § 102

Most issues raised in Applicant's arguments with respect to claims 1-10 as rejected previously under 35 U.S.C. § 102(b) are moot in view of the new ground(s) of rejection. Those

arguments considered to be relevant to the instant rejection have been considered and are addressed below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, and 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Schultze et al. (Structure 1994. 2:221-233), or Kuramoto et al. (Jpn. J. Cancer Res. 1992. 83:1128-1131)

The invention of the above claims is directed to an aptamer between 12 and 22 nucleotides, inclusive, wherein at least two G-rich regions exist, said G-rich regions selected from the group consisting of GGnG, GGGG, GnGG, nGGG, and GGGn. The invention is also drawn to said aptamer where the number of nucleotides separating each of the G-rich regions is 2 to 7, or 3 to 6, or 4, or where one of the at least two G-rich regions comprises GGnG, GnGG, or GGGn, wherein said aptamer competes for the binding site of SP1.

Schultze et al. teaches an oligonucleotide compound comprising d(GGGGTGGGG), which meets all the structural limitations of applicants' claimed invention.

Kuramoto teaches at least 15 G-rich oligos that meet the claimed limitations. Specifically Table III teaches an oligo with two G-quartets separated by four nucleotides that meets all the instant structural limitations.

Although the references do not specifically teach the claimed function of reducing CD28 expression in an activated human T-cell, the structures of Schultze et al. and Kuramoto et al. are substantially identical to applicants' claims and are thus considered to possess the functional limitation of reducing CD28 expression in an activated human T-cell in the absence of evidence to the contrary. As per MPEP 2112.01:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Therefore in the absence of evidence to the contrary, the invention as claimed by applicant is considered to be *prima facie* anticipated.

Allowable Subject Matter

Claims 11-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The sequences listed in each claim are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
May 5, 2003

Karen Lacourciere
KAREN LACOURCIERE
PATENT EXAMINER